COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.02.2002
C(2002) 494

NOT FOR PUBLICATION

COMMISSION DECISION

of 06.02.2002

amending Decision C(2000) 1407 on the marketing authorisation for the medicinal product for human use

" PegIntron - Peginterferon alfa-2b "

ONLY THE FRENCH AND THE DUTCH TEXTS ARE AUTHENTIC

(Text with EEA relevance)

COMMISSION DECISION

of 06.02.2002

amending Decision C(2000) 1407 on the marketing authorisation for the medicinal product for human use

" PegIntron - Peginterferon alfa-2b "

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1] as amended by Commission Regulation (EC) No 649/98,[2] and in particular Article 10(2) thereof,

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation (EEC) No 2309/93,[3] as amended by Commission Regulation (EC) No 1069/98,[4] and in particular Annex II thereto,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product “PegIntron - Peginterferon alfa-2b” entered in the Community register of medicinal products under Nos EU/1/00/131/001-030 authorised by Commission Decision C(2000) 1407 of 25 May 2000, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) SP Europe submitted an application on 30 January 2001 pursuant to Annex II to Regulation (EC) No 542/95 and Article 4(1) of Regulation (EEC) No 2309/93.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 20 September 2001 by the Committee for Proprietary Medicinal Products.

(4) Decision C(2000) 1407 should therefore be amended accordingly.

---

[1] OJ L 214, 24.8.1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 55, 11.3.1995, p. 15.
[4] OJ L 153, 27.5.1998, p. 11.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2000) 1407 is hereby amended as follows:

a) The following numbers are added to Article 1:

EU/1/00/131/031 – PegIntron - 50 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 50 µg (50 µg/0.5 ml) - 1 pen+1 injection needle+2 cleansing swabs

EU/1/00/131/032 - PegIntron - 50 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 50 µg (50 µg/0.5 ml) - 4 pens+4 injection needles+8 cleansing swabs

EU/1/00/131/033 - PegIntron - 50 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 50 µg (50 µg/0.5 ml) - 6 pens+6 injection needles+12 cleansing swabs

EU/1/00/131/034 - PegIntron - 50 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 50 µg (50 µg/0.5 ml) - 12 pens+12 injection needles+24 cleansing swabs

EU/1/00/131/035 - PegIntron - 80 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 80 µg (80 µg/0.5 ml) - 1 pen+1 injection needle+2 cleansing swabs

EU/1/00/131/036 - PegIntron - 80 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 80 µg (80 µg/0.5 ml) - 4 pens+4 injection needles+8 cleansing swabs

EU/1/00/131/037 - PegIntron - 80 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 80 µg (80 µg/0.5 ml) - 6 pens+6 injection needles+12 cleansing swabs

EU/1/00/131/038 - PegIntron - 80 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 80 µg (80 µg/0.5 ml) - 12 pens+12 injection needles+24 cleansing swabs

EU/1/00/131/039 - PegIntron - 100 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 100 µg (100 µg/0.5 ml) - 1 pen+1 injection needle+2 cleansing swabs

EU/1/00/131/040 - PegIntron - 100 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 100 µg (100 µg/0.5 ml) - 4 pens+4 injection needles+8 cleansing swabs

EU/1/00/131/041 - PegIntron -100 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 100 µg (100 µg/0.5 ml) - 6 pens+6 injection needles+12 cleansing swabs

EU/1/00/131/042 - PegIntron - 100 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 100 µg (100 µg/0.5 ml) - 12 pens+12 injection needles+24 cleansing swabs

EU/1/00/131/043 - PegIntron - 120 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 120 µg (120 µg/0.5 ml)-1 pen+1 injection needle+2 cleansing swabs

EU/1/00/131/044 - PegIntron - 120 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 120 µg (120 µg/0.5 ml) - 4 pens+4 injection needles+8 cleansing swabs

EU/1/00/131/045 - PegIntron - 120 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 120 µg (120 µg/0.5 ml) - 6 pens+6 injection needles+12 cleansing swabs

EU/1/00/131/046 - PegIntron - 120 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 120 µg (120 µg/0.5 ml) - 12 pens+12 injection needles+24 cleansing swabs

EU/1/00/131/047 - PegIntron - 150 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 150 µg (150 µg/0.5 ml)-1 pen+1 injection needle+2 cleansing swabs

EU/1/00/131/048 - PegIntron - 150 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use-Powder and solvent: two chamber cartridge (glass) in a pre-filled pen -150 µg (150 µg/0.5 ml) - 4 pens+4 injection needles+8 cleansing swabs

EU/1/00/131/049 - PegIntron - 150 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 150 µg (150 µg/0.5 ml) - 6 pens+6 injection needles+12 cleansing swabs

EU/1/00/131/050 - PegIntron - 150 micrograms - Powder and solvent for solution for injection in pre-filled pen - Subcutaneous use - Powder and solvent: two chamber cartridge (glass) in a pre-filled pen - 150 µg (150 µg/0.5 ml) - 12 pens+12 injection needles+24 cleansing swabs

b) The text set out in Annex I to this Decision is added to Annex I.

c) The text set out in Annex II to this Decision is added to Annex II.

d) The text set out in Annex III(A) and (B) to this Decision is added to Annex III(A) and (B) respectively.

Article 2

This Decision is addressed to SP Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – SP Europe, Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 06.02.2002

For the Commission
Erkki LIIKANEN
Member of the Commission